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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,715	07/20/2001	Brian J. Cox	18455.11	1492

25204 7590 10/30/2003

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EXAMINER	
PANTUCK, BRADFORD C	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 10/30/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,715	COX, BRIAN J.	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *11-17, 19, 27-32, 34-36, and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,18,20-26,33,37-41 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species 4, drawn to an apparatus for treating vascular aneurysms, in Paper No. 14 is acknowledged. The traversal is on the ground(s) that searching all of the pending claims is not unduly burdensome. This is not found persuasive because the invention clearly has multiple embodiments. A treatment device that looks like a stent and is meant for placement in a blood vessel is very different than a treatment device meant for placement inside of an aneurysm. The searches are not coextensive and each would require time searching in different subclasses.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because of the following informalities: In the Abstract, in lines 4-5, the phrase "The body member provide support mechanical support..." should be revised, as it is incorrect grammatically.

Appropriate correction is required.

Claim Objections

3. Claim 18 is objected to because of the following informalities: in line 8 of the claim (Presently Amended) the phrase "sia dat least" should be changed to "said at least". Appropriate correction is required.

4. Claim 18 is also objected to because of the following informalities: in lines 8-9, it is unclear what D and D' are referring to. It seems that it would be clearer if in the first instance of usage of these terms, the Applicant prefaced D with the word "diameter" so that it is clear that they are "diameter D" and "diameter D' ". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-10, 18, 20-26, 33, 37-41, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,769,882 to Fogerty et al. Regarding Claim 1, Fogerty discloses an apparatus for treating vascular aneurysms. His apparatus includes a support member (10) and a reactive material (14) [Column 8, lines 12-19] having a non-reacted state and a reacted state. Fogerty's reactive material, in fact, is a hydrogel and has an unswelled (non-reacted state) state and a reacted state, when it is swelled [Column 7, lines 22-32]. Because Fogerty's reactive material (14) is a hydrogel, just like the Applicant's, it will react in the same ways to the blood, and other internal fluids and proteins of the vasculature.

6. Regarding Claim 2, Fogerty discloses a support member (10), which is a tubular structure (22), as best seen in Figure 8. The tubular structure has many surfaces, most

obviously an internal surface and an external surface. The reactive material (24) is applied to the exterior surface of the support member (22).

7. Regarding Claim 3, the support member (10) having a tubular structure has an exterior surface. That exterior surface can be considered to have a left part and a right part. The reactive material (24) is shown covering both the left exterior surface and the right exterior surface in Fig. 8. One embodiment of Fogerty's invention is of the reactive material (24) covering the whole exterior of the graft (both the left exterior surface and the right exterior surface) [Column 6, lines 38-42]. The Applicant has not made any particular limitations on where the surfaces are or what they look like.

8. Regarding Claims 4 and 5, another embodiment of Fogerty's invention is applying the reactive material (14) to a portion of the first surface (left exterior surface) and a portion of the second surface (right exterior surface) [Column 6, lines 42-45]. Fogerty's reactive material coating takes the form of bands of coating applied to the exterior surface of the tubular member (10/22).

9. Regarding Claim 6, the Applicant is directed to Column 7, lines 33-43. There, Fogerty discloses a cuff, which can be considered to be a further extension of the support member. He says that the cuff is placed on the outside of the tubular member (10/22) and that that cuff can be partially made out of PTFE and partially out of a hydrogel [Column 7, lines 39-41]. In that instance, the hydrogel can be considered to be support member, as it is forming a part of the cuff that is a solid component, which (along with the tubular member) supports the interior wall of the vessel/aneurysm.

10. Regarding Claim 7, similarly to the above paragraph, the hydrogel, which forms part of the cuff, can be considered to be integrally formed with the other support members made up of PTFE. That is, the cuff consists of PTFE and hydrogel—the hydrogel support members are next to the PTFE support members of the fabric. The two are formed together, as one piece.

11. Regarding Claims 8 and 43, the cuff discussed above is a fabric and fabrics are made through weaving. Fogerty explains that the cuff *itself* is absorbable (Column 7, lines 33-34, and afterwards, that the cuff is made by weaving or knitting. Extrapolating, because he says, "the hydrogel can be placed inside the water permeable membrane," (lines 39-40) the hydrogel must be knitted into the PTFE fabric of the cuff.

Further, in Column 11 lines 3-8, Fogerty explains that his reactive material (14) may be formed into an unsupported *woven fabric*. In light of Fogerty's specification, an unsupported woven fabric implies that the fabric is made out of both hydrogel and another more hearty, strong material.

12. Regarding Claims 9 and 39, the reactive material of Fogerty's invention has a non-reactive volume of V and a reacted volume of V', wherein V' is larger than V. In Column 7, lines 3-7, Fogerty explains that the reactive material (14) may be a hydrophilic gel that absorbs body fluids to go from an assumedly smaller volume of V to a swelled, fluid-holding state with a volume of V'.

13. Regarding Claims 10 and 38, the reactive material is capable of obtaining a reacted volume V' in the presence of a physiological pH of about 7.4. *The normal pH*

of blood is between 7.35 and 7.45 [MedicineNet.com article], and because Fogerty's invention is meant to be applied to the inside of blood vessels, the reaction (swelling) will occur at a pH of about 7.4.

14. Regarding Claims 18 and 33, Fogerty discloses the invention as claimed. Fogerty discloses an apparatus for treating vascular aneurysms including a support member (10/22), which is radially and axially reticulated expanding stent with a cylindrical body. It has an internal lumen and many fenestrations (openings) because of its lattice shape, as is well known in the art, and specifically disclosed in Column 5, lines 52-57. The support member is expandable [Column 5, lines 38-51], and therefore in its unexpanded state will have a diameter D, and in its expanded state will have a diameter D', which is larger than D. Fogerty is very specific in that section about the precise dimensions of the expanded and unexpanded diameters. The tubular support member (10/22) has a reactive material [as more fully explained above], which is capable of restricting blood flow to the aneurysm [Column 6, lines 33-45]. Figure 4 shows the reactive material (14) blocking the blood, preventing it from entering the aneurysm (A).

15. Regarding Claims 20, 40, and 41 Fogerty's support member (10/22) is delivered to a site in a living body, using a balloon catheter and a guidewire [Column 9, lines 5-37].

16. Regarding Claim 21, a balloon catheter is a mechanical means of delivering the support member (10/22).

17. Regarding Claims 22 and 23, the support member contains an attachment device, such as adhesive [Column 6, lines 46-57]. Additionally, as also described in that passage, the reactive material (10) itself may serve as an anchoring device, disallowing the stent to move downstream of the aneurysm.

18. Regarding Claim 24, the support member is manufactured from the shape memory alloy, Nitinol [Column 6, lines 29-32].

19. Regarding Claim 25, the material comprising the support member may be radio-opaque [Column 6, lines 7-14].

20. Regarding Claim 26, Fogerty's support member can be made out of all of the materials disclosed as the applicant's support member, and will therefore have the same properties as the Applicant's. For that reason, although not specifically disclosed as "echo-genic," Fogerty's support member will have internal echoes, just like the Applicant's.

21. Regarding Claim 37, Fogerty discloses the method, as claimed, and as explained with reference to Claims 18 and 33 above. Fogerty's structure allows blood to flow through a blood vessel. Also, Fogerty's method includes activating a reactive material disposed on his device to restrict blood flow to an aneurysm [Column 6, lines 33-45]. One of the important ways in which Fogerty's reactive material (14) reacts within the body is to swell in the presence of a liquid such as blood.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

22. Claims 1, 8, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,596,296 to Nelson et al. Nelson discloses an apparatus capable of treating vascular aneurysms [Column 6 line 66 to Column 7 line 9] including both support members and a reactive material woven into the support members. If it is capable of holding a blood vessel open, than considered to be capable of holding a vessel with an aneurysm open as well. Nelson discloses making a stent by weaving hydrogel fibers with fibers of different materials. The hydrogel fibers are reactive, responding particularly to changes in temperature within the body [Column 20, lines 39-67]. The support members are made from various different polymers [Column 4, lines 52-56; Column 8, lines 55-58], blended or interwoven with the hydrogel [Column 6, lines 62-67; Fig. 1]. Nelson's hydrogels "undergo dramatic volume changes of 100 fold in response to a small (2-3C) temperature change," [Column 20, lines 52-55] and are therefore definitely capable of expanding the fabric of the stent in order to restrict blood flow to an aneurysm.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,015,431 to Thornton et al. [Column 8, lines 17-31; Fig. 2]

Publication No. US 2001/0000188 A1 to Lenker et al. {paragraph [0072] discusses making fibers of a graft out of hydrogels}

U.S. Patent No. 6,605,294 B2 to Sawhney [discusses treating aneurysms with hydrogels and polymers]

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

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